



Mitchell E. Daniels, Jr.
Governor

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State Health Commissioner

Indiana State Department of Health

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DATE: April 11, 2008

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CFSP
Manager, Food Protection Program

SUBJECT: Selenium in Samples of "Total Body Formula" and "Total Body Mega Formula"

From the information provided by FDA, the recalled dietary supplements linked to adverse reaction due to hazardous levels of selenium, were distributed nationwide. Detailed information about the products distribution has not been provided. Information is being provided in case of consumer inquiries.

Not classified; Hazardous dietary supplements; Recommend notification to health stores via phone, fax or e-mail.

Media Inquiries:

Kimberly Rawlings, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Finds Hazardous Levels of Selenium in Samples of "Total Body Formula" and "Total Body Mega Formula" Dietary supplement products linked to adverse reactions

The U.S. Food and Drug Administration announced today that it has found hazardous levels of selenium in samples of certain flavors of the dietary supplement products "Total Body Formula" and "Total Body Mega Formula." The FDA has received 43 reports of persons from nine states who experienced serious adverse reactions using these products.

On March 27, the FDA warned consumers not to purchase or use "Total Body Formula" in flavors Tropical Orange and Peach Nectar and "Total Body Mega Formula" in the Orange/Tangerine flavor of these products after receiving reports of adverse reactions in users in Florida and Tennessee (www.fda.gov/bbs/topics/NEWS/2008/NEW01812.html). The adverse reactions generally occurred after five to 10 days of daily ingestion of the product, and included significant hair loss, muscle cramps, diarrhea, joint pain, deformed fingernails, and fatigue.

Selenium, a naturally occurring mineral, is needed only in very small amounts for good health. Selenium can boost the immune system. Generally, normal consumption of food and water provides adequate selenium to support good health. Excessive intake of selenium is known to cause symptoms to include significant hair loss, muscle cramps, diarrhea, joint pain, fatigue, loss of finger nails and blistering skin.

Presently, FDA has 43 reports of adverse reactions including cases from Alabama, Florida, Georgia, Kentucky, Michigan, New Jersey, North Carolina, Tennessee, and Texas.

Analyses of samples of the products by FDA laboratories have now found most of the samples contain extremely high levels of selenium--up to 40,800 micrograms per recommended serving, or more than 200 times the amount of selenium per serving (i.e., 200 micrograms) indicated on the labels of the products.

The FDA continues to investigate the matter to determine how excessive amounts of selenium were added to the products.

FDA is advising consumers to stop using "Total Body Formula" in flavors Tropical Orange and Peach Nectar and "Total Body Mega Formula" in the Orange/Tangerine flavor and discard them by placing them in a trash receptacle outside of the home. "Total Body Formula" products are sold in eight-ounce and 32-ounce plastic bottles. "Total Body Mega Formula" is sold in 32-ounce plastic bottles. Both product lines are distributed by Total Body Essential Nutrition of Atlanta, which is listed on the products' labels.

Consumers who have been taking the products and have experienced adverse reactions should consult their health care professional. Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

The sole distributor of the "Total Body Formula" and "Total Body Mega Formula" products has voluntarily recalled the affected products. According to the company, the products were distributed nationwide.

More information about selenium and its toxic effects is available at this link to the Centers for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry: www.atsdr.cdc.gov/tfacts92.html.

